

We Claim:

1. A process, which comprises assaying a substantially pure amlodipine aspartate or amlodipine maleamide under a set of conditions to obtain a reference standard analytical result for said set of conditions.

2. The process according to claim 1, wherein said assay is thin layer chromatography and said conditions include the solvent, the concentration of amlodipine aspartate or amlodipine maleamide in said solvent, and the amount amlodipine aspartate or amlodipine maleamide applied to the chromatograph and wherein said reference standard analytical result is the R_f value and/or the size of a spot corresponding to said amlodipine aspartate or amlodipine maleamide.

3. The process according to claim 1, wherein said assay is HPLC and said conditions include the solvent, the concentration of amlodipine aspartate or amlodipine maleamide in said solvent, and the amount amlodipine aspartate or amlodipine maleamide applied to the chromatograph and wherein said reference standard analytical result is the resolution factor or retention time, peak area and/or the response factor of a peak corresponding to said amlodipine aspartate or amlodipine maleamide.

4. A process of testing purity or stability of a sample of amlodipine maleate or a pharmaceutical dosage form comprising amlodipine maleate which comprises assaying a sample of an amlodipine maleate substance or composition for the presence of amlodipine aspartate or amlodipine maleamide.

5. The process according to claim 4, which comprises:
assaying an amlodipine maleate substance or composition to obtain an analytical result; and
comparing said analytical result to a corresponding reference standard analytical result for amlodipine aspartate or amlodipine maleamide to determine if the purity or stability of said amlodipine maleate substance or composition is satisfactory.

6. The process according to claim 4, wherein said purity or stability is satisfactory if the amount of amlodipine aspartate or amlodipine maleamide relative to amlodipine maleate is determined to be less than 0.2 wt %.

7. A process for determining the presence of an impurity which comprises the steps of:

- a) dissolving a sample comprising amlodipine maleate in a solvent to produce a sample solution;
- b) dissolving a sample of amlodipine aspartate or amlodipine maleamide in a solvent to produce a reference solution;
- c) subjecting the sample solution and the reference solution to thin layer chromatography to obtain a TLC chromatogram for each; and
- d) estimating the intensity of any secondary spot obtained from the sample solution which corresponds in R_f value to the reference marker, against the intensity of the spot due to the aspartate or maleamide in the chromatogram of the reference solution.

8. A process for determining the presence of an impurity which comprises the steps of:

- a) dissolving a sample comprising amlodipine maleate in a solvent to produce one or more sample solutions;
- b) dissolving a sample of amlodipine aspartate or amlodipine maleamide in a solvent to produce a reference solution;
- c) injecting the sample and reference solutions into an HPLC column; and
- d) estimating the peak areas of each solution and calculating from these the content of the amlodipine aspartate or the amlodipine maleamide in each sample solution.

9. A process which comprises separating amlodipine maleate from either amlodipine aspartate or amlodipine maleamide.

10. The process according to claim 9, wherein said separation is carried out by thin layer chromatography.

11. The process according to claim 9, wherein said separation is carried out by HPLC.

12. A process, which comprises
blending amlodipine maleate with at least one pharmaceutically acceptable excipient to form a blend;
either (a) filling said blend into capsules or (2) compressing said blend in to tablets, to form a production lot of amlodipine maleate pharmaceutical solid dosage forms;
removing a sample of said amlodipine maleate pharmaceutical solid dosage forms from said production lot;
subjecting said sample to an assay to obtain a sample analytical result; and
comparing said sample analytical result to a corresponding reference standard analytical result for amlodipine aspartate or amlodipine maleamide to determine the amount of amlodipine aspartate or amlodipine maleamide relative to said amlodipine maleate; and
selling or releasing said production lot if the amount of amlodipine aspartate or amlodipine maleamide is not greater than 1.0 wt % based on the amount of amlodipine maleate.
13. The process according to claim 12, wherein said reference standard analytical result was determined prior to said blending step.
14. The process according to claim 13, wherein said comparing step uses an electronically stored representation of said reference standard analytical result.
15. The process according to claim 12, wherein said comparing step comprises a visual inspection of said sample analytical result and said reference standard analytical result.
16. The process according to claim 12, wherein said production lot is not released or sold if the amount of amlodipine aspartate or amlodipine maleamide is not greater than 0.2 wt % based on the amount of amlodipine maleate.